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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,327	01/29/2004	Randy Dean May	SP-03	1246
20985	7590	12/19/2005	EXAMINER	
FISH & RICHARDSON, PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			HANNAHER, CONSTANTINE	
			ART UNIT	PAPER NUMBER
			2884	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/766,327

Applicant(s)

MAY, RANDY DEAN

Examiner

Constantine Hannaher

Art Unit

2884

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

2. Section 608.01 of the MPEP states in part:

In order to minimize the necessity in the future for converting dimensions... to the metric system of measurements when using printed patents... all patent applicants should use the metric (S.I.) units followed by the equivalent English units when describing their inventions....

The Assistant Secretary and Commissioner of Patents and Trademark strongly reiterated and emphasized strong encouragement for patent applicants to use the metric system in patent applications in a message appearing at 1135 O.G. 55 dated February 18, 1992. At some future time, the USPTO will consider making it a requirement.

Note the use of the micron. The Examiner is unable to require the use of SI units.

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Note the use of "are disclosed" which can be implied.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 provides for the use of absorption spectroscopy, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 16 provides for the use of absorption spectroscopy, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 15 and 16 are rejected under 35 U.S.C. 101 because of the following reasons.

Claim 15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte*

Dunki, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 4-6, 10-13, 15, and 16 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by McVey (US006875399B2).

With respect to independent claim 1, and dependent claims 4-6, McVey discloses a system 10 (Fig. 2) for detecting ethylene oxide in air. See column 5, line 36 for the specific identification of “ethylene oxide” as a substitute for the hydrogen peroxide otherwise discussed in the specification. See column 5, line 23 for the specific identification of “air” as an example of a carrier gas in which the sterilant may be transported through the system. The system of McVey comprises a light source 100 emitting light at a wavelength in a range that anticipates the claimed wavelength (column 5, lines 5-8 and 16-18), wherein the light source 100 is positioned to emit light through a sample of air

(along path 104 in body 102 taking a sample of air from chamber 12, Fig. 1, through openings 106).

The system of McVey comprises a detector 96 configured to detect the intensity of light emitted from the light source (upon its passage along path 104 through the sample). The system of McVey comprises an electronics unit 16 coupled to the detector for determining the level of ethylene oxide in the sample of air (see column 9, lines 50-53 and column 10, lines 15-18 for the receipt of information from the receiving portion 94 of the system with detector 96, Fig. 2, and the determination of sterilant concentration in the chamber).

With respect to independent claim 7, and dependent claims 10 and 11; McVey discloses a system 10 (Fig. 2) for detecting ethylene oxide in air. See column 5, line 36 for the specific identification of "ethylene oxide" as a substitute for the hydrogen peroxide otherwise discussed in the specification. See column 5, line 23 for the specific identification of "air" as an example of a carrier gas in which the sterilant may be transported through the system. The system of McVey comprises a light source 100 emitting light at a wavelength in a range that anticipates the claimed wavelength (column 5, lines 5-8 and 16-18), wherein the light source 100 is positioned to emit light through a sample of air (along path 104 in body 102 taking a sample of air from chamber 12, Fig. 1, through openings 106). The system of McVey comprises a detector 96 configured to detect the intensity of light emitted from the light source (upon its passage along path 104 through the sample). The system of McVey comprises an electronics unit 16 coupled to the detector for determining the level of ethylene oxide in the sample of air (see column 9, lines 50-53 and column 10, lines 15-18 for the receipt of information from the receiving portion 94 of the system with detector 96, Fig. 2, and the determination of sterilant concentration in the chamber).

With respect to independent claim 12, McVey discloses a method for determining the level of ethylene oxide in a sample of gas corresponding to the illustrated system 10 (Fig. 2). See column

5, line 36 for the specific identification of "ethylene oxide" as a substitute for the hydrogen peroxide otherwise discussed in the specification. See column 5, line 23 for the specific identification of "air" as an example of a carrier gas in which the sterilant may be transported through the system. The method of McVey comprises the step of providing a light source 100 emitting light at a wavelength, positioning a detector 96 opposite the light source 100 to detect the level of emitted light (upon its passage along path 104 through the sample), supplying a sample of gas between the light source 100 and the detector 96 (through openings 106 in body 102), and detecting the amount of light passing through the sample of gas (by operation of the system). The Markush group is improperly written using "comprising" so it establishes no limitation on the wavelength which the light source must emit. The specific teachings of McVey, however, establish a range of wavelengths which *anticipates* at least one claimed wavelength (column 5, lines 5-8 and 16-18).

With respect to independent claims 15 and 16, McVey discloses a method for determining the level of ethylene oxide in air corresponding to the illustrated system 10 (Fig. 2) which would comprise the use of absorption spectroscopy in the wavelength range recited. See the explanation of the rejection of claim 12.

With respect to independent claim 13, McVey discloses a system 10 (Fig. 2) for detecting ethylene oxide in air. See column 5, line 36 for the specific identification of "ethylene oxide" as a substitute for the hydrogen peroxide otherwise discussed in the specification. See column 5, line 23 for the specific identification of "air" as an example of a carrier gas in which the sterilant may be transported through the system. The system of McVey comprises a light source 100 emitting light at a wavelength where ethylene oxide molecules absorb light at a substantially greater level than other molecules within air (see column 20, lines 51-55 for the specific teaching of measuring absorption at wavelengths where other vapor components contribute insignificantly or not at all, mandating that

the absorption of the sterilant be greater than that of the other components), wherein the light source **100** is positioned to emit light through a sample of air (along path **104** in body **102** taking a sample of air from chamber **12**, Fig. **1**, through openings **106**). The system of McVey comprises a detector **96** configured to detect the intensity of light emitted from the light source (upon its passage along path **104** through the sample). The system of McVey comprises an electronics unit **16** coupled to the detector for determining the level of ethylene oxide in the sample of air (see column 9, lines 50-53 and column 10, lines 15-18 for the receipt of information from the receiving portion **94** of the system with detector **96**, Fig. **2**, and the determination of sterilant concentration in the chamber).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 2, 3, 8, 9, 14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McVey (US006875399B2).

With respect to dependent claims 2 and 8, there should be no issue that lasers of the recited types were known at the time the invention is made and no citation is necessary. It would have been obvious to one of ordinary skill in the art at the time the invention was made that a laser of at least one of the recited types was suitable for use as the source **100**, **316** of the system of McVey in view of the requirement to produce infrared radiation of at least one selected wavelength (column 10, lines 29-31) and in view of their known properties of high brightness, low power consumption, wavelength selection, and the like.

With respect to dependent claims 3 and 9, there should be no issue that a detector of the recited type was known at the time the invention is made and no citation is necessary. It would have been obvious to one of ordinary skill in the art at the time the invention was made that a detector of the recited type was suitable for use as the detector **96** of the system of McVey in view of the requirement to quantitatively detect infrared radiation of at least one selected wavelength (column 10, lines 29-31) and in view of its known properties of low noise, good frequency response, quantum efficiency in the near infrared, and the like.

With respect to dependent claim 14, McVey discloses that the system further comprises a plurality of sample areas **A, B, C** each containing air that may contain ethylene oxide (column 6, lines 8-11). While the system of McVey places a corresponding plurality of probes **10** in these sample areas to pass air between a light source and a detector in the system **14**, selective delivery of air from the plurality of sample areas **A, B, C** to a single probe **10** would have been obvious to one of ordinary skill in the art at the time the invention was made to the extent that the necessary piping and valves was less burdensome than the provision of multiple probes, *i.e.*, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the multiple probes **10** in the system of McVey with a sample area selector selectively delivering air from the plurality of sample areas to a single probe **10** in order to avoid proliferation of multiple sources and multiple detectors and electrical cabling and power supplies and so forth.

With respect to independent claim 17, McVey discloses a system **312** (Fig. 10) for detecting ethylene oxide in air. See column 5, line 36 for the specific identification of "ethylene oxide" as a substitute for the hydrogen peroxide otherwise discussed in the specification. See column 5, line 23 for the specific identification of "air" as an example of a carrier gas in which the sterilant may be transported through the system. The system of McVey comprises a cell having two opposing

mirrors 340, 358, a light source 316 emitting light through the cell and configured as recited, a detector 360 configured as recited, electronics 16 coupled to the detector for determining the level of ethylene oxide in the gas, wherein the light source emits light approximately at a wavelength chosen from the group recited. The Markush group is improperly written using "comprising" so it establishes no limitation on the wavelength which the light source must emit. The specific teachings of McVey, however, establish a range of wavelengths which *anticipates* at least one claimed wavelength (column 5, lines 5-8 and 16-18). It would have been obvious to one of ordinary skill in the art that the cell having two opposing mirrors illustrated and described by McVey is a Herriott cell in view of the focusing mirrors 340, 358 and the multiple passes of the light through the cell.

Response to Submission(s)

12. This application has been published as US2004/0245471A1 on December 9, 2004.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Constantine Hannaher whose telephone number is (571) 272-2437. The examiner can normally be reached on Monday-Friday with flexible hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David P. Porta can be reached on (571) 272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ch


Constantine Hannaher
Primary Examiner